



This document is scheduled to be published in the Federal Register on 06/05/2015 and available online at <http://federalregister.gov/a/2015-13821>, and on FDsys.gov

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0207; FRL-9927-66]

Aluminum sulfate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of aluminum sulfate (CAS Reg. No. 10043-01-3) under 40 CFR 180.940(a). This regulation eliminates the need to establish a maximum permissible level for residues of aluminum sulfate.

DATES: This regulation is effective *[insert date of publication in the Federal Register]*. Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0207, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDNRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. *Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. *How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. *How Can I File an Objection or Hearing Request?*

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0207 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential

pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0207, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the **Federal Register** of May 2, 2012, (77 FR 25954) (FRL-9346-1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1E7933) by Exponent Inc., 1150 Connecticut Ave., NW, Suite 1100, Washington, DC 20036, on behalf of Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN, 55102. The petition requested that 40 CFR part 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of aluminum sulfate for use as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum end use concentration not to exceed 50 parts per million (ppm). That document referenced a summary of the petition prepared by the petitioner Exponent, Inc., which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is

a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by aluminum sulfate is discussed in this unit.

The acute oral toxicity of aluminum sulfate is low. The acute oral lethal dose (LD)₅₀ in male rats is >5,000 milligram/kilogram (mg/kg). No acute dermal or inhalation toxicity studies are available on aluminum sulfate. It is not a dermal irritant and is minimally irritating to the eyes. No skin sensitization studies are available.

The points of departure (PODs) used for the chronic and short-term risk assessments for aluminum sulfate were based on an Organization for Economic Cooperation and Development (OECD) Guideline 416, 2-generation rat oral reproduction study with aluminum sulfate (equivalent to OCSPP Harmonized Test Guideline 870.3800) in which the lowest-observed-adverse-effect level (LOAEL) was 188 milligram/kilogram/day (mg/kg/day) (equivalent to 37 mg aluminum (Al)/kg/day) based on decreased body weight from pups and parents and delay in vaginal opening. The no-observed-adverse-effect level (NOAEL) was 41 mg/kg/day aluminum sulfate (equivalent to 8.06 mg Al/kg/day).

Apart from the 2-generation rat oral reproduction study described above, limited data are available on aluminum sulfate. However, since ingested aluminum sulfate will readily dissociate in the stomach to aluminum (as will many other aluminum compounds), toxicology data on aluminum compounds as well as aluminum sulfate are considered in determining the acceptability and completeness of the toxicological data relevant to aluminum sulfate.

Aluminum compounds have been evaluated by the Agency for Toxic Substances and Disease Registry (ASTDR, 2008) and as part of the toxicological profile of aluminum, ASTDR notes that “There is a rather extensive database on the oral toxicity of aluminum in animals. These studies clearly identify the nervous system as the most sensitive target of aluminum toxicity and

most of the animal studies have focused on neurotoxicity and neurodevelopmental toxicity. Other adverse effects that have been observed in animals orally exposed to aluminum include impaired erythropoiesis in rats exposed to 230 mg Al/kg/day and higher; erythrocyte damage (as evidenced by decreases in hemoglobin, hematocrit, and erythrocyte osmotic fragility, and altered erythrocyte morphology) in rats exposed to 230 mg Al/kg/day and higher; increased susceptibility to infection in mouse dams exposed to 155 mg Al/kg/day; delays in pup maturation following exposure of rats to 53 mg Al/kg/day; and decreases in pup body weight gain in rats and mice exposed to 103 mg Al/kg/day and higher. Oral studies in rats and mice have not found significant histopathological changes in the brain under typical exposure conditions; however, altered myelination was found in the spinal cord of mouse pups exposed to 330 mg Al/kg/day on gestation day 1 through postnatal day 35. Overt signs of neurotoxicity are rarely reported at the doses tested in the available animal studies (≤ 330 mg Al/kg/day for bioavailable aluminum compounds); rather, exposure to these doses is associated with subtle neurological effects detected with neurobehavioral performance tests. Significant alterations in motor function, sensory function, and cognitive function have been detected following exposure to adult or weanling rats and mice or following gestation and/or lactation exposure of rats and mice to aluminum lactate, aluminum nitrate, and aluminum chloride. The most consistently affected performance tests were forelimb and/or hindlimb grip strength, spontaneous motor activity, thermal sensitivity, and startle responsiveness. Significant impairments in cognitive function have been observed in some studies, although this has not been found in other studies even at higher doses. Adverse neurological effects have been observed in rats and mice at doses of 100–200 mg Al/kg/day and neurodevelopmental effects have been observed in rats and mice at doses of 103–330 mg Al/kg/day.”

There are no available carcinogenicity studies with aluminum sulfate; however, in a cancer study with aluminum potassium sulfate, there were no exposure-related increased incidences of tumors, other proliferative lesions, or non-neoplastic lesions in B6C3F1 mice that ingested ≤ 979 mg Al/kg/day as aluminum potassium sulfate in the diet for 20 months. Based on this information, aluminum sulfate is not expected to be a carcinogen.

Specific information on the studies received and the nature of the adverse effects caused by aluminum sulfate as well as the NOAEL and the LOAEL from the toxicity studies are discussed in “Aluminum Sulfate: Human Health Risk Assessment and Ecological Effects Assessment for Proposed Exemption from the Requirement for a Tolerance When Used as an Inert Ingredient in Antimicrobial Pesticide Formulations Applied to Food-Contact Surfaces” in docket ID number EPA-HQ-OPP-2012-0267.

A. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological POD and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a RfD—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for aluminum sulfate used for human risk assessment is discussed below:

Acute Dietary Endpoint. No appropriate endpoint was identified from any of the aluminum sulfate studies in the database, including developmental toxicity studies in the rat. Consequently, EPA determined that there was no basis for selecting a dose and endpoint for an acute POD for the general population or females 13-49 years old.

Chronic Dietary Endpoint. A 2-generation reproduction study of aluminum sulfate in rats was considered critical in establishing the POD for chronic dietary risk assessment. The study supports a NOAEL of 41 mg/kg/day and a LOAEL of 188 mg/kg/day for decreased body weight in parents and pups and a delay in vaginal opening and should be used as the POD for all durations and exposure scenarios. An uncertainty factor (UF) of 100X (10X for interspecies extrapolation and 10X for intraspecies variation) is applied to obtain a chronic reference dose (cRfD) of 0.41 mg/kg/day. The Food Quality Protection Act (FQPA) factor is reduced to 1X. The chronic population adjusted dose (cPAD) is 0.41 mg/kg/day. This cPAD is protective of potential neurotoxicological effects of aluminum compounds.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Exposures to aluminum sulfate can occur following ingestion of foods with residues from food-contact surface sanitizing solutions for public eating places, treated dairy- and food-processing equipment and utensils as well as pre-harvest crop uses. In evaluating dietary exposure to aluminum sulfate, EPA considered exposure under the requested exemption from the requirement of a tolerance as well as exposures from existing uses of aluminum sulfate under the extant exemption from the requirement of a tolerance under 40 CFR 180.920. EPA assessed dietary exposures from aluminum sulfate in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide chemical, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for aluminum sulfate; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* The chronic dietary exposure assessment for this inert ingredient utilizes the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCID), Version 3.16, EPA, which includes food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, "What We Eat In America", (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model that assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts" (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738.

Additionally, a dietary exposure assessment of aluminum sulfate resulting from the requested use in antimicrobial food-contact surface sanitizing solutions was conservatively assumed that 100% of the diet results from food treated with food-contact surface sanitizers and that 100% of the sanitizing solution is transferred into food. A highly conservative model based on FDA assumptions regarding transfer of food contact sanitizing solution residues to food is utilized.

The dietary exposure values derived from both the conservative model used to estimate residues from application to growing crops are combined with the exposures estimated from the antimicrobial food-contact sanitizer uses.

iii *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that aluminum sulfate is not expected to pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for aluminum sulfate, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water

for the chronic dietary risk assessment of aluminum sulfate. This value was directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

There are no registered pesticide products containing aluminum sulfate as an inert ingredient for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found aluminum sulfate to share a common mechanism of toxicity with any other substances, and aluminum sulfate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that aluminum sulfate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In a 2-generation reproduction toxicity study, there was no evidence of increased susceptibility of infants and children to aluminum sulfate. In this study, the offspring and parental toxicity NOAEL was 41 mg/kg/day based on decreased weight gain in offspring, decreased body weight in parental animals, and a delay in vaginal opening seen at the LOAEL of 188 mg/kg/day.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for aluminum sulfate includes a 2-generation reproduction study, as well as chronic/carcinogenicity studies, mutagenicity studies, neurotoxicity studies and developmental neurotoxicity studies on other related aluminum compounds. The Agency concludes that for this ingredient, the results of these studies provide a reliable basis for assessing the range of potential effects to infants and children, such that the Agency has determined that no additional data are necessary at this time to evaluate effects to infants and children.

ii. There are available data on neurotoxicity and developmental neurotoxicity on aluminum compounds. The point of departure selected for risk assessment is based on a 2-generation rat reproductive toxicity study with aluminum sulfate, in which adverse effects were identified at dose levels below the dose levels at which neurotoxic effects or developmental neurotoxicological effects were observed and is therefore protective of those effects; no additional UFs are required to account for neurotoxicity.

iii. There is no evidence of increased susceptibility due to pre-or post-natal exposure to aluminum in infants and children.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and residues equivalent to the highest established tolerance-level residues for every food commodity. EPA made conservative (protective) assumptions utilizing a 100 ppb default value in the ground and surface water modeling used to assess exposure to aluminum sulfate in drinking water. In addition, highly conservative assumptions were utilized in assessing exposures to aluminum sulfate resulting from the proposed use in food-contact surface antimicrobial pesticide formulations. These assessments will not underestimate the exposure and risks posed by aluminum sulfate.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified, therefore, an acute dietary exposure assessment was not conducted.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to aluminum sulfate from food and water

will utilize 6.7% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term/intermediate-term adverse effect was identified; however, aluminum sulfate is not used as inert ingredient in any pesticide product registered for any use patterns that would result in short-term or intermediate-term residential exposure. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for aluminum sulfate.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in a rodent carcinogenicity study with aluminum potassium sulfate, aluminum sulfate is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to aluminum sulfate residues.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. EPA is establishing a limitation on the amount of aluminum sulfate that may be used in food-contact surface antimicrobial applications. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any food-contact surface antimicrobial applications for sale or distribution that contains greater than 50 ppm of aluminum sulfate by weight.

VIII. Conclusion

Therefore, an exemption is established for residues of aluminum sulfate for use as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum end use concentration not to exceed 50 ppm.

IX. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 29, 2015.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.940, add alphabetically the following inert ingredient to the table in paragraph (a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * *	* * *	*
Aluminum sulfate	10043-01-3	When ready for use, the end-use concentration is not to exceed 50 ppm
* * *	* * *	*

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